IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECRO GAINESVILLE LLC, Plaintiff, v. ACTAVIS LABORATORIES FL, INC., Defendant.	Civil Action No. 14-1118-GMS **CONSOLIDATED**

MEMORANDUM

I. INTRODUCTION

In this patent infringement action, Plaintiff Recro Gainesville LLC ("Recro") alleges infringement by Actavis Laboratories FL, Inc. of U.S. Patent No. 9,132,096 ("the '096 patent") and U.S. Patent No. 6,902,742 ("the '742 patent").[1] The court held a three-day bench trial in this matter on October 3, 4 and 7 of 2016. (D.I. 133–135). Presently before the court are the parties' post-trial proposed findings of fact and conclusions of law concerning infringement of the patents-in-suit. (D.I. 125, 126).

Pursuant to Federal Rule of Civil Procedure 52(a), and after having considered the entire record in this case and the applicable law, the court concludes that: (1) Actavis' proposed ANDA products infringe all of the asserted claims of the '096 patent; and (2) Actavis' proposed ANDA products infringe all of the asserted claims of the '742 patent. These findings of fact and conclusions of law are set forth in further detail below.

[1] Recro and Actavis submitted a Stipulated Dismissal of Claims and Counterclaims with Respect to U.S. Patent No. 6,228,398. (D.I. 117 at 1).

II. FINDINGS OF FACT[2]

A. The Parties

1. Plaintiff Recro Gainesville LLC ("Recro") is a Massachusetts limited liability company having its principal place of business at 1300 Gould Dr., Gainesville, GA 30504.

2. Defendant Actavis Laboratories FL, Inc. ("Actavis") is a Florida corporation having its principal place of business at 2945 W. Corporate Lakes Blvd, Weston, FL.

3. The court has subject matter jurisdiction, as well as personal jurisdiction over all parties.

B. Background

4. Recro has alleged infringement of U.S. Patent Nos. 6,902,742 ("the '742 patent") and 9,132,096 ("the '096 patent") against Actavis under 35 U.S.C. § 271(e)(2)(A).

5. Actavis asserted a defense of non-infringement of both the '096 and '742 patent.

C. The Patents-in-Suit

6. The '742 patent, entitled "Multiparticulate Modified Release Composition," issued on June 7, 2005, to Dr. Devane, Dr. Stark, Mr. Fanning, and Dr. Rekhi as named inventors. The face of the '742 patent claims priority to U.S. Patent Application No. 60/106,726, filed on November 2, 1998. According to the Orange Book, the expiration date of the '742 patent is November 1, 2019.

7. The '096 patent, entitled "Abuse Resistant Pharmaceutical Compositions," issued on September 15, 2015, naming Dr. Rekhi and Dr. Richard Sidwell as inventors. The face of the '096 patent claims priority to September 12, 2014. According to the Orange Book, the expiration date of the '096 patent is September 12, 2034.

1. The Asserted Claims

a. '096 Patent, Claims 1, 4, and 5

Claim 1, 4, and 5 of the '096 patent read:

1. An oral pharmaceutical composition comprising a first population of beads and a second population of beads; said first bead population comprising a pharmaceutically active ingredient

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[2] Prior to trial, the parties submitted an exhibit of uncontested facts in conjunction with their Pretrial Order. (D.I. 114, Ex. 1.) The court takes most of its findings of fact from the parties' uncontested facts. The court has also reordered and renumbered some paragraphs, corrected some formatting errors, and made minor edits for the purpose of concision and clarity that it does not believe alters the meaning of the paragraphs from the Pretrial Order. Otherwise, any differences between this section and the parties' statement of uncontested facts are unintentional.

The court's findings of fact with respect to matters that were the subject of dispute between the parties are included in Part III of this opinion ("Discussion and Conclusions of Law"), preceded by the phrase "the court finds" or "the court concludes."

selected from the group consisting of hydrocodone and pharmaceutically acceptable salts thereof, wherein said first bead population is substantially free of polyethylene oxide; and said second bead population comprising polyethylene oxide and a permeable or semi-permeable coating selected from the group consisting of an ammonio methacrylate copolymer, a methacrylic acid copolymer and a mixture thereof, wherein said second bead population is substantially free of any pharmaceutically active ingredient.

4. The composition according claim 1, wherein the pharmaceutically active ingredient is hydrocodone bitartrate.

5. The composition according to claim 4, wherein the hydrocodone bitartrate is present in an amount of from 5 to 250 mg.

b. '742 Patent, Claims 1, 6, 13, 14, 16, and 19

Claims 1, 6, 13, 14, 16, and 19 of the '610 Patent read:

1. A multiparticulate modified release composition comprising a first population of active ingredient-containing particles and at least one subsequent population of active ingredient-containing particles, the active ingredient contained in the first population being an opiate and the active ingredient in the subsequent population being an opiate or non-opiate, wherein the subsequent population of active ingredient-containing particles further comprise a modified release coating or, alternatively or additionally, a modified release matrix material, such that the composition following oral delivery to a subject delivers the active ingredients of the first and subsequent populations in a pulsatile manner.

6. The composition according to claim 1, wherein the subsequent population comprises opiate-containing particles.

13. The composition according to claim 6, wherein at least one of the active ingredients of the first and subsequent populations comprises hydrocodone or a pharmaceutically acceptable salt thereof, an enantiomer or mixtures thereof, or mixtures thereof.

14. The composition according to claim 1, wherein the first and subsequent populations have different in vitro dissolution profiles.

16. The composition according to claim 15, which in operation releases substantially all of the active ingredient from the first population prior to release of the active ingredient from the subsequent population.

19. The composition according to claim 16, wherein the mean in vitro dissolution profile in an aqueous medium is such that substantially all of the active ingredient of the first population is released within about two hours.

D. Zohydro® ER

8. Zohydro® ER extended-release capsules contain hydrocodone bitartrate and are indicated "for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." Recro licenses the '742 and '096 patents to Pernix Therapeutics Holdings, Inc. ("Pernix") and Pernix markets and sells Zohydro® ER capsules in the United States.

9. The '742 and '096 patents have been listed in the Orange Book in connection with Zohydro® ER capsules.

E. Actavis' ANDA

10. Actavis submitted ANDA No. 206952 to the FDA seeking approval to market hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths.

11. By letter dated August 12, 2014, Actavis advised Recro's predecessor that it had submitted ANDA No. 206952 to the FDA seeking approval to manufacture, use, or sell generic hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths prior to the expiration of the '742 patent.

12. By letter dated April 6, 2015, Actavis advised Recro that it had submitted an amendment to ANDA No. 206952 seeking approval to manufacture, use, or sell generic hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths prior to the expiration of the'742 patent.

13. By letter dated November 10, 2015, Actavis advised Recro that it had submitted ANDA No. 206952 to the FDA seeking approval to manufacture, use, or sell generic hydrocodone bitartrate extended-release capsules in the 10, 15, 20, 30, 40, and 50 mg strengths prior to the expiration of the '096 patent.

14. Recro asserts infringement of the following claims against Actavis: claims 1–4, 6, 9, 13-14, 16 and 19 of the '742 patent; and claims 1–2 and 4–5 of the '096 patent.

15. C.A. No. 14-1118-GMS commenced on September 3, 2014, before the expiration of 45 days from receipt of Actavis's August 12, 2014 notice letter. C.A. No. 15-413-GMS commenced on May 21, 2015, before the expiration of 45 days from receipt of Actavis's April 6, 2015 notice letter. C.A. No. 15-1196-GMS commenced on December 23, 2015, before the expiration of 45 days from Recro's receipt of Actavis's November 10, 2015 notice letter. The 30-month stay deadline against Actavis is February 12, 2017.

III. DISCUSSION AND CONCLUSIONS OF LAW

The court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b), (c), and (d), and 1400 (b). After

having considered the entire record in this case, the substantial evidence in the record, the parties' post-trial submissions, and the applicable law, the court concludes that Actavis' proposed products infringe all of the asserted claims of the '096 and '742 patents. The court's reasoning follows.

A. Infringement

1. The Legal Standard

The determination of whether an accused method infringes a claim in a patent has two steps: (1) construction of the claim to determine its meaning and scope; and (2) comparison of the properly construed claim to the method at issue. *See Tanabe Seiyaku Co. v. United States Int'l Trade Comm'n,* 109 F.3d 726, 731 (Fed. Cir. 1997) (citing *Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd* 517 U.S. 370 (1996)). The patent owner has the burden of proving by a preponderance of the evidence that "every limitation of the patent claim asserted to be infringed is found in the accused [method], either literally or by equivalent." *SmithKline Diag., Inc. v. Helena Lab. Corp.,* 859 F.2d 878, 889 (Fed. Cir. 1988). Under this standard, a patent owner does not have to produce "definite" proof of infringement, but must instead demonstrate that "infringement was more likely than not to have occurred." *See Warner- Lambert Co. v. Teva Pharms., USA, Inc.,* 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005) (citing *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.,* 261 F.3d 1329, 1336 (Fed. Cir. 2001)). The application of a patent claim to an accused product is a fact-specific inquiry. *See Kustom Signals, Inc. v. Applied Concepts, Inc.,* 264 F.3d 1326, 1332 (Fed. Cir. 2001).

Even if an accused product differs enough from the claimed product to preclude literal infringement, the patent owner can establish infringement under the doctrine of equivalents. *Zelinski v. Brunswick Corp.*, 185 F.3d 1311, 1316 (Fed. Cir. 1999). The doctrine of equivalents analysis seeks to determine "if there is equivalence between those elements of the accused

product and the claimed limitations of the patented invention that are not literally infringed." *Id.* Elements of the allegedly infringing device and the claimed device are considered equivalent if the differences between the elements are insubstantial. *Id.* "One test used to determine 'insubstantiality' is whether the element performs substantially the same function in substantially the same way to obtain substantially the same result as the claim limitation." *Id.* at 1316–17.

In the ANDA context, 35 U.S.C. § 271(e)(2)(A) provides that it shall be an "artificial" act of infringement to submit an ANDA "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." 35 U.S.C. § 271(e)(2)(A). The filing of an ANDA only constitutes a technical act of infringement for "purposes of creating case or controversy jurisdiction." *Ferring B.V. v. Watson Labs., Inc.-Florida*, 764 F.3d 1401, 1408 (Fed. Cir. 2014). Once jurisdiction is established, the ultimate infringement inquiry is determined by traditional patent law principles, requiring "a comparison of the asserted patent claims against the product that is likely to be sold following ANDA approval." *Id.*

2. The '096 Patent

Recro asserts that Actavis' ANDA products infringe claims 1, 4, and 5 of the '096 patent. The focus of the dispute concerns one claim limitation: "a permeable or semi-permeable coating selected from the group consisting of an ammonio methacrylate copolymer, a methacrylic acid copolymer and a mixture thereof." JTX3, col 30 ll. 8–12. Recro argues that Actavis' ethylcellulose-based coating is equivalent to the claimed polyacrylic coatings—"ammonio methacrylate copolymer, a methacrylic acid copolymer and mixtures thereof." *Id.*; D.I. 126 at 20. Actavis contends that not only does their ethylcellulose-based coating fail to satisfy the function-way-result test, *see Zelinski*, 185 F.3d at 1316–17, it also includes a cellulosic polymer

that Recro dedicated to the public and other excipients not permitted by the claims. (D.I. 125 at 8–13).

a. Dedication to the Public

Actavis maintains that Recro dedicated ethylcellulose to the public because cellulosic polymers were disclosed in the specification, but not claimed. (D.I. 125 at 8). Disclosure dedication occurs when the patentee "discloses but declines to claim subject matter." *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002). Allowing the patent holder to then recapture that subject matter under the doctrine of equivalents conflicts with a patent claim's purpose to clearly define the scope of the patentee's right. *Id.* The Federal Circuit has held, however, that the written description's disclosure of alternatives to the claimed subject matter does not always dedicate those alternatives to the public. *See id.* ("This 'disclosure-dedication' rule does not mean that any generic reference in a written specification necessarily dedicates all members of that particular genus to the public."). The disclosure in the specification must be specific enough that a skilled artisan "could identify the subject matter that has been disclosed and not claimed." *Id.* The court does not find that the disclosure of cellulosic polymers dedicates ethylcellulose to the public.

The court heard testimony that ethylcellulose is one of many cellulosic polymers known to those having ordinary skill in the art. Dr. Siepmann testified that there are many thousands of cellulosic polymers in existence, and several dozen that are commonly used in pharmaceutical formulations. Trial Tr. 113:19–114:2. After mentioning that suitable coating materials include cellulosic polymers generally, the patent lists types of those polymers "such as cellulose acetates, cellulose alkanylates and cellulose acrylates." JTX3, col. 5 ll. 13–15. Dr. Felton, Actavis' expert, stated that ethylcellulose would not fall into any of the subcategories listed after the

disclosure of general cellulosic polymers." Trial Tr. 364:1–365:5. The court is therefore persuaded by Recro's point that, though those having skill in the art might recognize ethylcellulose as one choice of cellulosic polymer, the specification actually leads one away from that choice. (D.I. 126 at 9).

The written description and the claims provide notice to the public "as to the subject matter of the patent," and "the scope of the invention," respectively. *PSC Computer Prod., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1358 (Fed. Cir. 2004). The quintessence of such public notice is the ability to determine what has been taught by the specification and what has been claimed. *See id.* at 1360. The court finds that a person skilled in the art would not have been able to clearly identify that ethylcellulose was disclosed and not claimed, given the generality of the phrase "cellulosic polymers." The court finds, therefore, that ethylcellulose was not dedicated to the public.

b. Doctrine of Equivalents

Recro concedes that the Actavis does not literally infringe the asserted claims of the '096 patent. (D.I. 126 at 5). Instead, Recro contends that Actavis' ethylcellulose-based coating "is equivalent to the claimed coatings 'consisting of an ammonio methacrylate copolymer, a methacrylic acid copolymer and mixtures thereof.'" (D.I. 126 at 4 (citing JTX3, col. 30 ll. 8–12)). The court finds Recro's argument persuasive because the ethylcellulose-based coating performs substantially the same function, in substantially the same way, to obtain the same result. *See Zelinski,* 185 F.3d at 1316–17.

The specification of the '096 patent explicitly states that the functions of the placebo bead coating are to "provide a physical barrier essentially separating or sequestering the gelling agent from the other components of the composition" and to "control (i.e. delay or otherwise limit) the

ingress of water into the second bead population, thus restraining the gelling action of the gelling agent." JTX3, col. 4, l. 66–col. 5, l. 6. Defendants' expert, Dr. Felton, testified that ethylcellulose "is the semipermeable membrane that controls the water ingress into the bead." Trial Tr. 296:20–22. Defendants ANDA also characterizes ethylcellulose as a polymer "widely used in oral pharmaceutical formulations as a binder, extended release polymer and hydrophobic coating agent for tablets and granules." JTX35 at 31. Additionally, in discussing the effect of the pH of the dissolution medium on drug release, Actavis explained to the FDA that ethylcellulose was selected as the "release controlling polymer" because, in the presence of liquid, it exhibits "pH independent swelling and permeating of drug molecules across the membrane." JTX35 at 21. The court finds that Defendants statements in the ANDA and Dr. Felton's testimony support Plaintiffs' assertion that the ethylcellulose-based coating performs the same function as the claimed polyacrylic coatings. *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248 (Fed. Cir. 2000) (holding that courts can consider statements made in the ANDA to instruct their infringement analysis).

The claimed polyacrylic coating behaves differently depending on how it is used. When the claimed composition is administered orally and intact the "[w]ater from the surrounding environment is absorbed through the coating of the gelling agent-containing beads which, upon contact with the gelling agent, causes the beads to swell." JTX3, col. 9 ll. 33–36. Eventually, the swelling of the beads causes the coating to rupture. *Id.* ll. 36–38. Though rupture of the gelling-agent containing beads causes the gelling agent to form a viscous mass, the gel does not interfere with the release of the drug from the active ingredient-containing beads when taken as directed. *Id.* ll. 45–49. This is due to how the bead population disperses along the gastrointestinal tract. *Id.* ll. 31–33. When the claimed composition is crushed or dissolved in a

small amount of water, however, the gelling agent creates a viscous mass, trapping the active ingredient, and assuring that it cannot be drawn up into a syringe. *Id.* ll. 50–55.

Defendant's expert, Dr. Felton, testified that ethylcellulose in Actavis' placebo beads functions to restrict the ingress of fluid into the bead and is often used in the preparation of pharmaceutical coatings capable of rupture. Trial Tr. 355:17–25. The rupturable nature of the ethylcellulose-based coating is clear from the examples adduced at trial demonstrating the "rupture sequence" of both an ethylcellulose based coating and the methacrylate coating. PTX 56 (methacrylate coating); PTX 68 (ethylcellulose coating). The sequences appear substantially similar, if not identical.

Dr. Felton explained that the way Actavis' product works is that if it is ingested as a capsule, "the capsule [will] dissolve, and the individual beads, both drug containing bead and placebo, a gelling bead, will separate, and as long as they separate sufficiently far away from each other, then they won't interfere with the release of the active ingredient." Trial Tr. 354:19–25. Dr. Felton agreed with Plaintiff's counsel that Actavis' product has abuse deterrent properties without changing the in vitro release of hydrocodone when the product is used as intended. Trial Tr. 355:1–5. The Addendum to Product Development Report for Actavis' generic product supports Dr. Felton's testimony, attesting to the fact that "[t]he presence of placebo beads is not intended to alter the drug sequence." JTX35 at 20. The court finds that the combination of the statements in the ANDA along with Dr. Felton's testimony is enough to conclude that Actavis' ethylcellulose-based coating functions in substantially the same way as the claimed coating.

Lastly, the result of the polyacrylic coating in the placebo bead is that it deters abuse when the product is crushed or dissolved in a small amount of water. *See* Trial Tr. 111:11–13.

When taken as directed, however, it allows the patient to receive the same in vivo active-ingredient exposure as they would without the coating. *Id.* Dr. Felton testified that Actavis' placebo beads achieve the same result. See Trial Tr. 355:1–5.

Defendants argue Plaintiffs failed to prove infringement under the doctrine of equivalents because Plaintiff's expert, Dr. Siepmann, did not properly account for the excipients in Actavis' coating. (D.I. 125 at 11). Defendants contend that because the claim language requires the coating be "selected from the group consisting of an ammonio methacrylate copolymer, a methacrylic acid copolymer and a mixture thereof," the presence of any other excipients is explicitly excluded. *Id.* The court is not persuaded.

The court finds that excipients are not excluded by the language of claim 1 of the '096 patent. In *Warner Chilcott Co., LLC v. Zydus Pharmaceuticals (USA) Inc.*, No. CA 11-1105-RGA, 2013 WL 1729383 (D. Del. Apr. 22, 2013), Judge Andrews confronted a very similar issue to the one the court faces here—does a Markush group limit "the entirety of the 'inner coating layer' to the specifically listed polymers?" *Id.* at *5. Judge Andrews concluded that a person having ordinary skill in the art would not find excipients excluded from the Markush claim because excipients, solvents, and carriers are "naturally associated with pharmaceutical formulations." *Id.* Excipients, therefore, could be understood to be unrelated to the actual invention because they were not used in a novel fashion. *Id.* The court finds that identical reasoning can be applied here.

Although the claim phrase "consisting of" is ordinarily found to signify exclusion, in the '096 patent, "consisting of" only serves to limit the universe of polymers that can be present in the coating. The phrase does not limit the presence of excipients, solvents or carriers ubiquitous to pharmaceutical preparations. Dr. Felton testified that triethyl citrate was a common excipient

in drug coatings. Trial Tr. 360:7–8. The '096 patent itself also states that "[t]he coating may further comprise plasticizers, pore forming agents, anti-adherents or other excipients." JTX3, col. 5 ll. 24–26. The court thus finds that excipients like talc and triethyl citrate are not excluded by Markush claim style.

Defendants maintain that because triethyl citrate is a pore former, its presence in Actavis' placebo bead coating could impact its function, undermining the doctrine of equivalents analysis. (D.I. 125 at 11–12). The court finds Defendant's argument unconvincing given its statements in the ANDA. Defendants acknowledged that triethyl citrate could alter the permeability characteristics of the coating. JTX030 at 51. They represented to the FDA, however, that "the risk of [t]riethyl [c]itrate affecting dissolution is low because it's [sic] level of use in the current formulation is fixed at 10 weight percent of the ER." *Id.* In fact, Defendants explicitly stated that both triethyl citrate and talc have a "negligible effect on drug dissolution." *Id.* at 56. As a result, the court finds that the presence of excipients in Actavis' coating does nothing to undermine the doctrine of equivalents analysis.

c. Dependent Claims 4 and 5

There is really no dispute that Actavis' ANDA product meets the limitations of dependent claims 4 and 5. Claim 4 discloses "[t]he composition according to claim 1, wherein the pharmaceutically active ingredient is hydrocodone bitartrate." JTX3, col. 30 ll. 19–20. Claim 5 requires a "composition according to claim 4, wherein the hydrocodone bitartrate is present in an amount of from [sic] 5 to 250 mg." JTX3, col. 30 ll. 21–23.

Actavis' ANDA document discloses a "[q]uality [t]arget [p]roduct [p]rofile (QTPP) for [h]ydrocodone [b]itartrate ER [c]apsules" where the dosage strength is 10, 15, 20, 30, 40, and 50

milligrams. JTX30 at 4, 16–17. The court thus finds that Actavis' ANDA product infringes dependent claims 4 and 5 in addition to independent claim 1.

3. The '742 Patent

Recro asserts that Actavis' product infringes claims 1, 6, 13, 14, 16, and 19 of the '742 patent. The dispute centers around two claim limitations: (1) "comprising a first population of active ingredient-containing particles and at least one subsequent population of active ingredient-containing particles," JTX2 col. 15 ll. 61–64; and (2) "delivers the active ingredients of the first and subsequent populations in a pulsatile manner." *Id.* col. 16 ll. 4–5. Recro argues that Actavis' products literally infringe both claim limitations, and alternatively that Actavis' product infringes the first claim limitation under the doctrine of equivalents. (D.I. 126 at 12–15).

a. A first and subsequent population of active ingredient-containing particles

The '742 patent specification lists a multitude of multiparticulate modified release compositions. The patent states that typically, "the dosage form may be a blend of different populations of active ingredient containing particles which make up the immediate release and the modified release components, the blend being filled into suitable capsules." JTX2, col. 10 ll. 38–42. The patent also explains that the different populations of active ingredient-containing particles can be compressed into "mini-tablets," or further, formed into a multilayer tablet. *Id.* ll. 43–48.

The evidence presented at trial demonstrated that Actavis' active ingredient-containing beads do not comprise a first and subsequent population of active ingredient containing particles. Instead, Actavis' product can be described as a multilayer tablet. Dr. Felton described a tablet where a drug layer, containing hydrocodone, polyethylene glycol, and water, is layered on top of a sugar sphere. Trial Tr. 309:21–312:25. A release controlling barrier is subsequently layered

on top of the drug layer, and on top of the barrier layer, there is another drug layer, again with hydrocodone bitartrate, polyethylene glycol, and water. *Id.* Recro argues that Actavis' product still falls within the scope of the claim because the specification explicitly allows for a multilayer tablet. The patent makes clear, however, that the first and second population of particles are different from each other—"the subsequent population of active ingredient-containing particles further comprises a modified release coating or, alternatively or additionally, a modified release matrix material." JTX2, col. 15 ll. 67–col. 16 ll. 3. As Dr. Felton stated, both active ingredient layers are *the same*. The subsequent drug layer, as Dr. Felton called it, does not comprise a modified release coating or a modified release material. The release-controlling barrier layer is *on top* of the layer containing the active-ingredient.

Recro argues that Actavis' product does, in fact, have two populations of active ingredient-containing particles—one with a sugar sphere, a drug layer, and an extended release coat and another with just a sugar sphere and a drug layer. (D.I. 126 at 13–14). Dr. Siepmann, Recro's expert, testified that what Actavis' essentially did was take the "particle" without the extended release coat and put it on to the "particle" with the extended release coat. Trial Tr. 85:12–20. The court finds Recro's argument unpersuasive. The claim requires that the particles, *plural*, comprise a modified release coating. JTX2, col. 15 ll. 67–col. 16 ll. 3. According to Dr. Siepmann's testimony, there would only be one active ingredient-containing particle with an extended release coating in each of Actavis' pellets. Thus, from a semantic perspective, a sugar sphere with a drug layer and an extended release layer cannot be considered a subsequent population of active ingredient-containing particles.

In the alternative, Recro tries to argue that the active-ingredient-containing particles are the individual particles of hydrocodone contained in Actavis' pellets. Again, the court is not

persuaded. Hydrocodone bitartrate is present in the pellets as a crystal. Even Dr. Siepmann, refers to the active ingredient as a drug crystal. Trial Tr. 91:5–6. It is unclear to the court what could be considered an active-ingredient containing particle in a layer that could more aptly be described as a population of polyethylene glycol, water, and drug crystals. Moreover, claim 1 of the '742 patent requires that the active ingredient-containing particles themselves comprise the modified release coating or the modified release matrix material. JTX3, col. 16 ll. 1–3. Recro offers no arguments for how that is possible given their alternate construction for active ingredient-containing particles.

Because the court concludes that Actavis does not literally infringe the first and subsequent population of active ingredient-containing particles limitation, it must determine whether Actavis infringes under the doctrine of equivalents. Recro maintains that, even assuming Actavis' product does not contain a first and subsequent population of active ingredient-containing particles, there is no substantial difference between Actavis' approach and the claimed approach. (D.I. 126 at 14). Dr. Siepmann testified that the function and result of both the one- and two-pellet approach are to "deliver the drug in a specific manner," i.e. a pulsatile manner. Trial Tr. 87:8–10, 25–88:1. The court finds that the active ingredient in Actavis' product, with first and subsequent active ingredient-containing layers separated by a release-controlling barrier, is delivered in a pulsatile manner, *see infra* § III.A.3.b–c. Accordingly, the court moves on to analyzing whether pulsatile delivery is achieved in the same way by the claimed product and Actavis' product.

The specification of the '742 patent makes clear that active ingredient is released from the first population of active ingredient-containing particles, followed by a subsequent release of active ingredient-containing from the second population of particles. JTX2, col. 4 ll. 37–48. The

patent also allows for situations where the first population releases the active ingredient rapidly and the second population releases the active ingredient over an extended period of time. JTX2, col.8 ll. 35–44. The ANDA reveals a very similar mode of action. In Actavis' product, the "two-stage coating" works by releasing twenty percent of the total dose immediately, followed by the extended release of eighty percent of the dose. JTX20 at 20. So regardless of whether the first and subsequent releases of active ingredient come from different layers of one multilayer tablet or different particles all together, the releases are achieved in the same way; the first release occurs from the first population of particles or a first layer, and a subsequent release occurs from a second population of particles or a second layer. Because the court finds that Actavis' multilayer tablet differs insubstantially from Recro's claimed first and subsequent population of active ingredient-containing particles, Actavis' product meets the first limitation of claim 1.

The court wishes to note that the La Manna reference played no role in its analysis. It is not clear to the court whether Actavis is trying to use the reference to assert a theory of prosecution history estoppel or whether Actavis is simply trying to underscore its point that its multilayer tablet with a discrete barrier layer would not be equivalent to claimed dosage form. (D.I. 125 at 14). Either way, the statements made to the Patent Office during the prosecution of the La Manna application have no effect on Recro's ability to assert infringement under the doctrine of equivalents. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 734 (2002) (explaining that if the original patent application once claimed the purported equivalent, but during patent prosecution the patentee narrowed the claim to obtain the patent, the patentee cannot later recapture that subject matter through the doctrine of equivalents).

The statements made with regard to the La Manna reference were made on January 11, 2007, long after the '742 patent issued on June 7, 2005. *See id.* at 724 ("Estoppel arises when an amendment is made to secure the patent and the amendment narrows the patent's scope."). Though prosecution history of a related application may limit application of the doctrine of equivalents in a *later* filed patent, *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1322 (Fed. Cir. 1999) (emphasis added), it can by no means affect the application of the doctrine of equivalents in an earlier filed patent without vitiating the very purpose of the doctrine. Here, the statements clearly were not made to secure the patent considering they were made after the '742 patent issued. For that reason, the court declines to consider the statements made to the Patent Office during prosecution of the La Manna patent.

b. Delivers the active ingredients of the first and subsequent populations in a pulsatile manner

Claim 1 of the '742 patent requires that following oral delivery, the composition "delivers the active ingredients of the first and subsequent populations in a pulsatile manner." JTX2, col. 16 ll. 4–5. The court's December 29, 2015, claim construction order construed the phrase to mean "following oral delivery to a subject provides a first pulse of an active ingredient release, followed by at least one subsequent pulse of active ingredient release, producing a plasma concentration profile characterized by two or more peaks interspersed with low concentration troughs." (D.I. 69 at 1–2).

Recro argues that Actavis' dissolution data disclosed in the ANDA demonstrated that the release from its products involves two pulses of active ingredient. (D.I. 126 at 16). Actavis counters that the term "pulse" would be synonymous with "burst" to a person of skill in the art. Trial Tr. 329:23–24. The court finds that regardless of what a person having ordinary skill in the art would interpret the term "pulse" to mean, a "burst" of active ingredient is not required by the

patent or the court's claim construction. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) ("[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification."). Accordingly, the court finds Actavis' argument unpersuasive on this point.

The '742 patent explains that "[t]he number of pulses in the profile . . . in operation will depend on the number of active ingredient containing components in the composition." JTX2, col. 6 ll. 16–19. Embodiments listed in the patent specification also allow for a number of combinations of active ingredient-containing components. The first component can be an immediate release or a time-delayed immediate release component. JTX2, col. 8 ll. 5–10. The second component can be a time-delayed immediate release, a time-delayed sustained release or an extended release component. JTX2, col. 8 ll. 11–16. Because the patent states that the number of pulses will depend on the number of active ingredient-containing components, and such an interpretation does not interfere with the court's claim construction ruling, the court finds that Actavis' product meets that limitation.

Actavis' ANDA states that the goal of the company's research and development efforts was to create a dosage form that provided an initial rapid release followed by a sustained release. JTX30 at 46. They achieved that goal by "loading 80% of the dose onto active pellets that were coated with an ER coat" and then, on top of the ER coat, applying "an over-coat of [h]ydrocodone [b]itartrate equivalent to 20% of the dose." *Id.* The type of active ingredient-containing components used in Actavis' product—immediate and extended release components—fall within the scope of claim 1 of the '742 patent. Interpreting the claim term "pulse" in accordance with Dr. Felton's proposed construction—essentially requiring two

immediate-release components—would cause a preferred embodiment to fall outside of the claim scope. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) (explaining that an interpretation that reads a preferred embodiment out of the claim scope is rarely, if ever, correct). Because Actavis' product contains two active ingredient-containing components falling within the scope of claim 1, as evidenced by its statements in the ANDA, the court finds that Actavis product meets the first and subsequent pulse claim limitation in claim 1 of the '742 patent.

The applicant's discussion of the Paradissis reference during prosecution of the parent of the '742 patent, U.S. Patent No. 6,228,398, does nothing to undermine the court's findings. The Paradissis reference taught a pharmaceutical composition "comprising 0-50% of an immediate release particle and up to 100% of an extended release particle capable of approaching a zero order release rate of a drug during a 12 to at least 24 hour period." DTX512 at 5. The applicants explained that a zero order release rate meant that the drug was released at a constant rate over time. *Id.* The Applicants contrasted that release rate with the pulsatile release of their own drug, which, they stated, "means a first pulse of active ingredient release is followed by a period of negligible active ingredient release, the period of negligible active ingredient release is followed by at least one second pulse of active ingredient release." DTX512 at 5–6.

Actavis tries to argue that the period of negligible release is somehow required by the claims because of the applicant's statements with regard to this parent application. (D.I. 125 at 17). Actavis also interprets the term "zero-order release rate" to mean a "sustained release system designed to release the drug over an extended time frame." *Id.* First, the court's claim construction does not require a negligible release of active-ingredient. (D.I. 69 at 1–2). Further, the prosecution history establishes that Paradissis could be a one hundred percent extended

release particle with a constant release rate. Actavis' product is certainly not analogous to the product disclosed in the Paradissis reference. Actavis' own ANDA states that the goal of their research and development work was to "formulate a dosage form that provides an initial rapid release followed by a sustained release," not a one hundred percent extended release particle. JTX30 at 46. The Paradissis reference, therefore, has no effect on the court's infringement analysis of the pulsatile release claim limitation.

c. Plasma concentration characterized by two or more peaks interspersed with low concentration troughs

As previously mentioned, the court construed claim 1 to require not just a first and subsequent pulse of active ingredient, but also "a plasma concentration profile characterized by two or more peaks interspersed with low concentration troughs." (D.I. 69 at 2). Actavis contends that its three bioequivalence studies show no evidence that administering its product to patients causes plasma concentration profiles that meet the court's construction. (D.I. 125 at 18–19). Recro argues, however, that because some patients experienced plasma concentration profiles characterized by two or more peaks interspersed with low concentration troughs, Actavis' product meets the claim limitation. (D.I. 126 at 18). The court finds Recro's argument persuasive.

It is well established that a finding of direct infringement can be predicated on circumstantial evidence demonstrating that at least one person directly infringed an asserted claim. *See Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1364 (Fed. Cir. 2012); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009); *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 850 (Fed. Cir. 2010). Further, claim 1 of the '742 patent references "oral delivery to a subject." The court construed "a subject" in accordance with its plain and ordinary meaning. (D.I. 69 at n.1). The facts at issue here bear a striking resemblance to those analyzed

by Chief Judge Stark in *Research Found. of State Univ. of N.Y. v. Mylan Pharm. Inc.*, 809 F. Supp. 2d 296 (D. Del. 2011), *vacated-in-part on other grounds*, 531 F. App'x 1008 (Fed. Cir. 2013).

In *Research Found.*, Mylan maintained that their generic drug did not infringe the claimed drug because it did not meet the claim limitation requiring a "steady state blood concentration of doxycycline of between 0.3 μg/ml to 0.8 μg/ml." *Id.* at 330. Mylan presented evidence at trial that the mean minimum blood concentration value of 31 subjects was 0.164 μg/ml. *Id.* Chief Judge Stark found that the claims-at-issue were not directed to mean values, however. The claims instead were directed to administering a single pill and treating a single patient. *Id.* Accordingly, the court held that "even if only 1 of 31 subjects in the pivotal pK study had a C_{min} of 0.3 to 0.6 μg/ml, [that was] a sufficient basis from which to find infringement." *Id.* at 330–31. The court finds Recro's analysis of individual subject's plasma concentration profiles proper given *Research Found.* and the claim limitation's focus on administering the composition to a subject.

Here, Recro presented evidence that at least seven individuals in the ACT-15030 bioequivalence study had plasma profiles exhibiting two or more high concentration peaks interspersed with low concentration troughs. JTX41 at 2–7. The 15030 study reported subject's plasma concentration levels between zero and thirty hours after they were given ten milligrams of hydrocodone bitartrate extended release capsules. *Id.* Recro's expert, Dr. Fleckenstein, showed that subject 1028 in the ACT-15030 study exhibited the claimed plasma concentration profile. Trial Tr. 205:17–206:1. Dr. Fleckenstein presented both the data from Actavis' 15030 clinical study report, JTX41 at 2, and his own graph of that data. PDX236. Dr. Fleckenstein explained that subject 1028 exhibited a rapid absorption of the drug indicated by a sharp rise in

hydrocodone concentration in the subject's blood—from zero concentration upon administration to 7.613 hydrocodone concentration after two hours. JTX41 at 2; Trial Tr. 205:17–22. At three hours, subject 1028 had a hydrocodone plasma concentration level of 6.927, a drop from the peak experienced at two hours. Dr. Fleckenstein explained that this was the low concentration trough required by claim 1 because it was consistent with the dissolution data reported in Actavis' ANDA. Trial Tr. 229:5–14.[3]

Dr. Fleckenstein summarized all of Actavis' in vitro dissolution tests found in Actavis' ANDA. JTX45 at 51, 54, 57, 60, 63, 66, 117, 129, 141, 153, 165, 177; PDX223. The dissolution data from the Clinical Summary section of the ANDA, for the six different dosage forms (10mg–50mg), had sampling times at 0, 1, 2, 4, 6, 8, 10, 12, 14, and 16 hours. JTX45 at 51, 54, 57, 60, 63, 66. Dr. Fleckenstein testified that hydrocodone, being a highly soluble compound, dissolves very rapidly. Trial Tr. 192:6–10. It was, therefore, important to have more frequent sampling times than each hour. More frequent sampling was specifically needed for at least the first four hours because that is when the dissolution rates are rapidly changing due to the combination of and extended release layer and immediate release layer in Actavis' product.

[3] Dr. Fleckenstein also pointed to data in the Zohydro® New Drug Application ("NDA"), JTX10 at 93, to support his testimony that Actavis' ANDA product likely had a "two to two and a half hour lag time built in before release of the second component." Trial Tr. 206:2–6. The court could not consider that data, however. "It is error for the court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent." *Zenith Labs v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994). There is an exception to that maxim where the commercial embodiment meets all of the claim limitations. *See Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1288 (Fed. Cir. 2010). Upon analysis of the Zohydro® NDA, the court realized that it likely made an error in its *Markman* Opinion. *See* (D.I. 69 at 1–2). As previously mentioned, the court construed "pulsatile manner" in claim 1 of the '742 patent to mean "producing a plasma concentration profile characterized by two or more peaks interspersed with low concentration troughs." *Id.* After analyzing the NDA, it appears that Zohydo®, for which the '742 patent is listed in the Orange Book, does not even meet the pulsatile release claim limitation as construed by the court. Figure 45 in the NDA—a graphical representation of the in vitro mean plasma concentration levels of hydrocodone over time—shows no sign of the "low concentration trough" required by the court's construction. JTX10 at 81. During claim construction, the court did not have the benefit of the data disclosed in the NDA, however. To be clear, Actavis' product infringes the "pulsatile" limitation of claim 1 as the court construed it. The court simply wishes to note that: (1) it is possible that the court's construction of "pulsatile manner" would have been different if the NDA had been before it during claim construction; and (2) it would constitute clear error for the court to credit Dr. Fleckenstein's testimony comparing Actavis' product to Zohydro®.

Trial Tr. 249:5–9. Dr. Fleckenstein used the control group data from Actavis' alcohol dose dumping study to get more frequently sampled data for his analysis of the dissolution rate of Actavis' product. *Id.* at 192:13–16.

The table that Dr. Fleckenstein created, using both the alcohol dose dumping control group data and the general dissolution studies' mean data, demonstrates that in the first fifteen minutes after administration of the ANDA product, nineteen percent of the hydrocodone dissolved. PDX224; Trial Tr. 193:16–21. Over the next fort-five minutes, another nineteen percent slowly dissolved. Trial Tr. 193:22–25. Between one and four percent dissolved every fifteen minutes until the two-hour time-point. PDX224. Between two and four hours, and additional twenty-five percent of the total hydrocodone dissolved. *Id.* Between the four- and six-hour time-points, only another thirteen percent of the total hydrocodone dissolved. *Id.* The court finds that Dr. Fleckenstein's analysis of the dissolution data shows an immediate release between zero and fifteen minutes. *Id.* There is then a slower rate of release over the next hour and forty-five minutes, where only another nineteen percent in total is released. *Id.* There is then another release somewhere between the two- and four-hour time-points because the percent dissolved increased during that two-hour window. *Id.* After the four-hour time-point, the amount of hydrocodone dissolved between each time-point slowly declined. *Id.* The court finds that Dr. Fleckenstein's testimony, along with the dissolution data, support the assumption that the dip in subject 1028's plasma profile actually reflects the low-concentration trough required by the claims. If there is another release of hydrocodone from the subsequent layer between two and four hours after administration, it follows that there would be a dip in the amount of hydrocodone present in the subject's blood prior to that release because the body has metabolized most of the initial release. *See* Trial Tr. 217:22–218:24.

Some subjects, like subject 1018, exhibited low concentration dips in their blood plasma profiles after 4 hours. JTX41 at 2, 5. Dr. Fleckenstein distinguishes those dips from the actual low concentration trough associated with Actavis' drug delivery system by explaining that, according to the clinical protocol, the subjects were fed after four hours. Trial Tr. 208:13–20. Dr. Fleckenstein explained that food will "stimulate flow to the liver" and cause "variability in the clearance of the drug." *Id.* The court finds Dr. Fleckenstein's testimony credible. It is also buttressed by Actavis' own data stating that "[i]nter-assay precision of the assay was determined by the % [coefficient of variation] of the [quality control] samples for Hydrocodone from all acceptable batches and it ranged from 2.7 to 3.3%." JTX33 at 22. The high accuracy of the assay employed directly contradicts Actavis' explanation for why the court must consider mean subject plasma concentration data—"the assay that is used [] could contribute to variability." (D.I. 125 at 21). The court thus finds that Actavis' product meets the plasma profile limitation of claim 1 of the '742 patent because at least some patients exhibited the claimed profile.

Actavis instructs the court to consider the mean values for the group of subjects because of the variability in an individual's blood concentration over time. (D.I. 125 at 21); Trial Tr. 442:1–8. Again, the court finds that argument unavailing. Dr. Fleckenstein testified that because of the complicated absorption characteristics for hydrocodone, there will be a lot of intra-subject variability—each subject will absorb and metabolize the drug slightly differently. Trial Tr. 217:22–218:24. If anything, the intra-subject variability underscores the importance of analyzing individual data because, as Plaintiff's Expert, Dr. Fleckenstein, testified, "the use of mean values would 'average [] out' the variability and smooth out the profiles." (D.I. 126 at 18 (citing Trial Tr. 204:14–205:2)).

Actavis also takes issue with the fact that "Dr. Fleckenstein's conclusions rely on single-point dips in blood plasma concentration levels in 16 out of the 112 subjects in the three studies conducted." (D.I. 125 at 21). Recro persuasively points out, however, that the patent does not require a particular patent curve shape with specific peak height and trough depths. (D.I. 126 at 19). The patent explains that those in the art are aware that the plasma concentration curve will be influenced by the active ingredient used, the delay in release of the active ingredient from each component, the coatings used in or on the components, and the nature of release from the components. JTX2, col. 8 ll. 1–27. "Depending on the duration of the lag time between the release of active ingredient from each component and the nature of the release . . . the pulses in the plasma profile may be well separated and clearly defined peaks . . . or the pulses may be superimposed to a degree . . . ." JTX2, col. 8 ll. 27–34. Neither the patent nor the court's claim construction require a specific amount of time for which a peak or a trough must persist. Actavis' arguments on this point do nothing to undermine the court's finding that Actavis' product meets the claimed plasma profile limitation.

d. Dependent claims 6, 13, 14, 16, and 19

Dependent claim 6 of the '742 patent discloses the "composition according to claim 1, wherein the subsequent population comprises opiate-containing particles." JTX2, col. 16 ll. 15–17. Actavis' ANDA clearly states that the extended release layer comprises hydrocodone. JTX35 at 28. Trial testimony established that hydrocodone bitartrate is an opioid. Trial Tr. 178:11–12. Actavis, therefore infringes claim 6 of the '742 patent.

Claim 13 of the '742 patent requires "[t]he composition according to claim 6, wherein at least one of the active ingredients of the first and subsequent populations comprises hydrocodone or a pharmaceutically acceptable salt thereof." JTX2, col. 16 ll. 36–40. The

ANDA establishes that both layers—the immediate release and extended release layers—of Actavis' product comprise hydrocodone. JTX35 at 28.

Claim 14 requires "[t]he composition according to claim 1, wherein the first and subsequent populations have different in vitro dissolution profiles." JTX2, col. 16 ll. 41–43. The combination of the average dissolution data from Actavis' in vitro dissolution studies and the more frequently sampled data from the alcohol dose dumping studies clearly indicate different in vitro dissolution profiles for the immediate release and extended release components of Actavis' product.

Actavis disclosed in its ANDA that the initial rapid release followed by a sustained release was achieved "by loading 80% of the dose onto active pellets that were coated with an ER coat," and then loading "[o]n top of the ER coat, an over-coat of [h]ydrocodone [b]itartrate equivalent to 20% of the dose." JTX30 at 46. The average dissolution data that Dr. Fleckenstein collated into a chart, PDX224, and a graph, PDX225, demonstrated that nineteen percent of the hydrocodone in the product dissolved within the first 15 minutes of administration. JTX45 at 117, 129, 141, 153, 165, 177. Another nineteen percent dissolved over the next hour and forty-five minutes. *Id.* At two hours, thirty-eight percent of hydrocodone had dissolved, and at four hours sixty-three percent had dissolved. JTX45 at 51, 54, 57, 60, 63, 66. The amount dissolved slowly decreased for the remaining time points—6, 8, 10, 12, 14, and 16. *Id.* The rate of dissolution was never as high as it was in the first fifteen minutes. Trial Tr. 193:16–21. The dissolution data that Dr. Fleckenstein presented at trial clearly matched the goals of Actavis' formulation as outlined in their ANDA. *See* JTX30 at 46. About twenty-percent of the drug dissolved immediately, and the remaining eighty-percent of hydrocodone that came from the

layer behind the extended-release coating, dissolved slowly over the remaining fifteen hours and forty-five minutes. JTX45 at 51, 54, 57, 60, 63, 66, 117, 129, 141, 153, 165, 177.

Dr. Fleckenstein also presented evidence allowing the court to conclude that the immediate release of twenty-percent of hydrocodone does, in fact, come from the first active ingredient layer of Actavis' product, whereas the extended dissolution of eighty-percent of Actavis' product comes from the subsequent active ingredient containing layer of Actavis' product. PDX227. Dr. Fleckenstein analyzed the ANDA dissolution data for just the extended release component of Actavis' drug. JTX43 at 2; JTX42 at 1. Dr. Fleckenstein testified that he subtracted the dissolution percentage for the extended release form of the drug from the total percentage dissolved at those time points disclosed in the in vitro dissolution studies. Trial Tr. 194:22–195:5. This analysis demonstrated that, in the first hour, most of the dissolution of the drug comes from the first active-ingredient containing layer, with only an average of nine-percent of the extended release component contributing to the total amount dissolved. PDX227; JTX43 at 1,2. Recro persuaded the court that it is more likely than not that Actavis' product infringes claim 14 of the '742 patent.

Claim 16 discloses a form of the composition of claim 1 where "substantially all of the active ingredient from the first population" is released "prior to release of the active ingredient from the subsequent population." JTX2, col. 16 ll. 48–51. As previously mentioned, Actavis loaded twenty-percent of the hydrocodone dose in a layer on top of the extended release layer. Actavis intended for the top active ingredient-containing layer to release immediately upon administration to the subject. JTX30 at 46. Dr. Fleckenstein's chart, PDX229, summarizing the data disclosed in Actavis' ANDA, demonstrates that within the first fifteen minutes after administration of the drug, nineteen-percent of hydrocodone is dissolved. JTX45 at 117, 129,

141, 153, 165, and 177. The first active-ingredient containing layer in Actavis' product contains twenty-percent of the total amount of hydrocodone. The data also demonstrates that only an average of nine-percent of the extended release component is released within the entire first hour. JTX35 at 42; PDX227. Accordingly, the court finds that the first active ingredient layer released substantially all of the active-ingredient prior to the release of active ingredient from the subsequent layer found under the extended release coating.

Claim 19 requires that mean, in vitro dissolution profiles demonstrate that "substantially all of the active ingredient of the first population is released within about two hours." JTX2, col. 16 ll. 64–67. For the reasons previously stated, this claim is clearly infringed by Actavis' product. In fact, substantially all of the active ingredient is released from the first active ingredient-containing layer within the first fifteen minutes after administration.

B. Remedies

Under 35 U.S.C. § 271(e)(4)(A), the effective date of any Food and Drug Administration approval of Actavis' ANDA No. 20-6952 shall be a date not earlier than the later expiration date of the '096 and '742 patents, including any extensions and marketing exclusivities (September 12, 2034). Pursuant to 35 U.S.C. § 271(e)(4)(B), the court finds that Actavis, its officers, agents, attorneys, and employees, and those acting in privity or concert with any of them, should be enjoined from engaging in the commercial manufacture, use, offer to sell, or sale with the United States, or importation into the United States of Actavis' ANDA Product prior to the expiration of the '096 and '742 patents.

IV. CONCLUSION

In sum, the court finds infringement of all of the asserted claims of the '096 and '742 patents.

Dated: February 24, 2017

UNITED STATES DISTRICT JUDGE